510(k) Summary of Safety and Effectiveness for the Hoffmann® II Dynamization/Distraction Rod-to-Rod Coupling

Proprietary Name:	Hoffmann® II Dynamization/Distraction Rod-to-Rod Coupling
Common Name:	External Fixation Frame Component
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Regulatory Class:	Class II
Device Product Code:	87 LXT
For Information contact:	Karen Ariemma, Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone: (201) 760-8187 Fax: (201) 760-8435

Intended Use:
This submission describes an external fixation frame component which, when used together with the components of the Hoffmann® II External Fixation System, the Monotube® Triax™ External Fixation System, and Apex™ Pins, creates an external fixation frame construct. This device is used to provide stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting.

Description:
The subject Hoffmann® II Dynamization/ Distraction Rod-to- Rod Coupling is designed to connect either a 20 mm diameter Monotube® Triax™ Dynamization/Distraction Rod or a 20 mm diameter Monotube® Triax™ Carbon Tube to a Hoffmann® II 8 mm diameter aluminum, carbon fiber or stainless steel rod. The Hoffmann® II Dynamization/ Distraction Rod-to-Rod Coupling is manufactured from stainless steel and aluminum.

Substantial Equivalence:
Equivalency of this device is based on similarities in intended use, materials, design and operational principles to the Hoffmann® II Compact™ Compression/Distraction Rod-to-Rod Coupling, K971755 and the Hoffman® II Articulation Coupling, K952730. Testing has been conducted on the Hoffmann® II Dynamization/ Distraction Rod-to-Rod Coupling demonstrating substantial equivalence to the predicate Hoffmann® II Articulation Coupling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401

Re: K003211
Trade Name: Hoffman II Dynamization/Distraction Rod-To-Rod Coupling
Regulatory Class: Class II
Product Code: KTT and LXT
Dated: October 12, 2000
Received: October 13, 2000

Dear Ms. Ariemma:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003211

Device Name: Hoffmann® II Dynamization/Distraction Rod-to-Rod Coupling

Indications For Use:

The Hoffmann® II Dynamization/Distraction Rod-to-Rod Coupling is intended to be used in conjunction with the components of the Hoffmann® II External Fixation System, the components of the Monotube® TRIAX™ External Fixation System and the Apex™ Half Pins of the Hoffmann® External Fixation System.

This device is used to provide stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts, or other means of internal fixation. The indications for use of metallic external fixation devices include:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003211

Prescription Use____ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)